

THE CAMBRIDGE STATISTICS DISCUSSION GROUP

(PLEASE NOTE CHANGE OF TITLE)

Monday 7th October 2002 7:15 for 7:45

Large Lecture Theatre,  
MRC Cognition and Brain Sciences Unit,  
Chaucer Road, Cambridge

## Strategies for Optimisation and Variance Reduction in Method Development & Validation

**Ian MacPherson**

PRISM Training & Consultancy Ltd, Cambridge

**Abstract:** The process of validating a new assay or method ("is the assay/method/... fit for its purpose") inevitably requires regulatory aspects to be addressed and acceptance criteria to be satisfied. Statistical procedures such as Design of Experiments (DoE) and variance component estimation should, however, be adopted further upstream during the development phase - indeed, this is recommended by the regulatory authorities. The presentation will describe how such techniques can be applied during the development and validation stages in a structured and sequential fashion using simple software tools in order to prevent problems and/or failure to comply, rather than troubleshooting and late fixes.

**Speaker:** Ian MacPherson has over 20 years experience in the pharmaceutical industry, having supported various areas of non-clinical research and development and seen various mergers and harmonisations with Wellcome, SmithKline & French, Beecham and finally SmithKline Beecham. He left a management role in the latter just over a year ago to form PRISM Training & Consultancy Ltd with a colleague, aimed at supporting experimenters in any research, development or manufacturing environment through provision of training, consultancy and software development.

**Annual General Meeting:** Ian's talk will be preceded by a brief Annual General Meeting.

**Directions** Chaucer Road is off Trumpington Road - if you are heading away from the city centre it is the first right after the junction with Brooklands Avenue. Number 15 is at the end on the left and is a large Victorian House with a more modern extension to its right. The entrance is in the porch located in the middle of the older section on the left as you come in and is accessed by ascending a few steps from the car park. Cars may be parked there. The outside door will be locked at 7:45.

**Provisional Next Meetings:**

27th November - David Spiegelhalter (MRC Biostatistics).

3rd February - Christine Fletcher (AMGEN).

May - Peter Wadhams (Scott Polar) on 'Statistical Properties of Sea Ice Thickness - is the Arctic Ice Disappearing?'.

**Supper:** Some members eat before a talk at the University Centre meeting in the downstairs bar at 6pm. All welcome!

**Secretary:** Peter Watson, MRC Cognition and Brain Sciences Unit, 15 Chaucer Road, Cambridge CB2 2EF;

telephone 01223 355294 Extension 801; E-mail [peter.watson@mrc-cbu.cam.ac.uk](mailto:peter.watson@mrc-cbu.cam.ac.uk)

**For security purposes could you please let Peter Watson know if you intend attending the talk.**

**TURN OVER for the Annual General Meeting agenda**

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## **Annual General Meeting**

The annual general meeting will be followed immediately by Ian MacPherson's talk 'Strategies for Optimisation and Variance Reduction in Method Development & Validation'.

### **Agenda:**

0. Approval of Minutes of previous A.G.M.
1. Treasurer's Report.
2. Secretary's Report.
3. Election of Chairman, Secretary, Treasurer, plus 3 other members of the Committee.
4. Any Other Business.

### **Rules for Election:**

1. FRANCISE: All paid-up members may vote or stand for office.
2. NOMINATIONS: The offices to be filled are Chairman, Secretary and Treasurer and three other members of the Committee.

An outgoing Chairman will be a member of the Committee ex officio. At the end of each year the entire Committee will stand down, but may stand again for the same office as they are leaving without nomination. To be elected to a different office a candidate must be nominated by one person from the paid-up membership, not including himself. Nominations do not require a seconder to be valid, but do require the consent of the nominee. One person can be nominated for more than one office, but hold only one. If a person is elected to a higher office (according to the ordering given below) he or she automatically ceases to be a candidate for a lower office. A candidate for the post of Chairman, Secretary, Treasurer is automatically a candidate for the Committee if he or she fails to gain election to one of these three posts.

**TURN OVER for the directions to the Large Lecture Theatre and the abstract of Ian's talk**